

# PATENT COÖPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference P27126PC00/RR	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/NL2005/000168	International filing date ( <i>day/month/year</i> ) 08 March 2005 (08.03.2005)	Priority date ( <i>day/month/year</i> ) 09 March 2004 (09.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ADVANCED PROTECTIVE INJECTION SYSTEMS (A.P.I.S.) B.V.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
  2. This REPORT consists of a total of 8 sheets, including this cover sheet.
- In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report 13 September 2006 (13.09.2006)</td> </tr> <tr> <td style="padding: 2px;">Authorized officer  Nora Lindner  e-mail: pt02@wipo.int</td> </tr> </table>	Date of issuance of this report 13 September 2006 (13.09.2006)	Authorized officer  Nora Lindner  e-mail: pt02@wipo.int
Date of issuance of this report 13 September 2006 (13.09.2006)			
Authorized officer  Nora Lindner  e-mail: pt02@wipo.int			

# PATENT COOPERATION TREATY

REC'D 21 JUL 2005

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From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

15/9

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing **25 JULY 2005**  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/NL2005/000168

International filing date (day/month/year)  
08.03.2005

Priority date (day/month/year)  
09.03.2004

International Patent Classification (IPC) or both national classification and IPC  
A61M5/50, A61M5/315

Applicant  
ADVANCED PROTECTIVE INJECTION SYSTEMES ...

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl  
Fax: +31 70 340 - 3016

Authorized Officer

Sedy, R

Telephone No. +31 70 340-2978



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/NL2005/000168

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 19-22

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):  
☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 19-22 are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.  
☐ no international search report has been established for the whole application or for said claims Nos.  
☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.  
☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
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PCT/NL2005/000168

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	6-16
	No: Claims	1-5,17-22
Inventive step (IS)	Yes: Claims	10,11,13,15
	No: Claims	1-9,12,14,16-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III.**

- 1 The wording "described as a component of the injection syringe..." used in claims 19-22 is unclear because it does not specify any technical features of the claimed devices. Therefore, it is not possible to give an opinion on novelty and inventive step, Article 6 PCT.

**Re Item V.**

- 1 Reference is made to the following document:

D1: EP-A-0 704 225 (BECTON, DICKINSON AND COMPANY; BECTON DICKINSON AND COMPANY) 3 April 1996 (1996-04-03)  
D2: EP-A-0 282 097 (HABLEY MEDICAL TECHNOLOGY CORPORATION) 14 September 1988 (1988-09-14)  
D3: WO 92/18181 A (GALLO, MICHELE, ANTONIO) 29 October 1992 (1992-10-29)  
D4: US-B1-6 494 863 (SHAW THOMAS J ET AL) 17 December 2002 (2002-12-17)  
D5: EP-A-1 184 049 (BECTON DICKINSON CO) 6 March 2002 (2002-03-06)  
D6: US-A-5 380 295 (VACCA ET AL) 10 January 1995 (1995-01-10)

**2 INDEPENDENT CLAIM 1**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (see e.g. column 9, lines 17-30, figures 2, 6-11)(the references in parentheses applying to this document):

Injection syringe (20) with retractable injection needle (37), having:

- a liquid container (21) having a needle opening (63);
- a plunger/plunger rod assembly (42), which is moveable over a certain travel in the liquid container (21) and comprises a plunger rod (43), plunger and a plunger head (46);

- an injection needle (37) with needle mount (28) which, in an active position (*see e.g. figure 1*), projects out of the liquid container (21) through the needle opening (63) and, in a retracted position (*see e.g. figure 11*), is located fully within the liquid container (21);
- a travel limiter which comes into action after an injection has been administered, using the injection syringe (20) and subsequently the injection needle (37) with needle mount *have* been moved into the retracted position by the plunger/plunger rod assembly (42) being retracted, after which it restricts the plunger/plunger rod assembly (42) in the event of a movement towards the needle opening (63), in such a manner that the injection needle (37) cannot be pushed out of the liquid container (21),

the travel limiter having a stop mechanism having a stop face (54) associated with the plunger/plunger rod assembly (42), and having a stop face (70) associated with the liquid container (21), it being possible for at least one stop face to be displaced between an initial, inactive position (*see e.g. figure 1*), in which an injection can be administered using the injection syringe (20), and an active position (*see e.g. figure 11*), in which the stop faces (54, 70) actively come into contact with one another and thereby limit the travel of the plunger/plunger rod assembly (42).

2.2 As such, this document discloses all the features of claim 1 so that its subject-matter is not new in the sense of Article 33(2) PCT.

2.3 Moreover, in addition to D1, also D2 and D3 (see passages referred to in the search report) represent prior art documents which clearly disclose an injection syringe as claimed in claim 1.

### 3 DEPENDENT CLAIMS 2-22

Dependent claims 2-9, 12, 14, 16-18 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). See for example:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

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**3.1 novelty**

D1, column 9, lines 17-30, figures 2, 6-11, for **claims 2-5 and 18**;

D2, column 7, lines 29-36, for **claim 17**;

**3.2 inventive step**

D4, column 12, lines 11-20, figures 17-19, for **claims 6-9 and 14**;

D5, column 9, lines 13-46, column 9, line 56 to column 10, line 23, figures 5,6, for **claim 12**;

D6, figure 3, for **claim 16**.

**3.3 DEPENDENT CLAIMS 10, 11, 13, 15**

The combination of the features of dependent claims 10, 11, 13, 15 is neither known from, nor rendered obvious by, the available prior art. Specifically, it is not obvious to provide "an activation element having a locking means suitable for locking the activation element in the position in which the one or more stops are active" since it cannot be derived in an obvious manner from the cited documents.

**Re Item VIII.**

**1 CLAIM 10:**

The features following the expression "preferably" are to be regarded as entirely optional. Consequently, it is not clear if these features should or should not be regarded as being included into the scope of the claim, therefore rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.